PUBLIC HEALTH COUNCIL

A regular meeting of the Public Health Council of the Massachusetts Department of Public Health was held on Tuesday, January 24, 2006, 10:00 a.m., at the China Trade Center, 2 Boylston Street, Daley Conference Room, Boston, Massachusetts. Public Health Council Members present were: Chair Paul J. Cote, Jr., Ms. Phyllis Cudmore, Mr. Manthala George, Jr., Ms. Maureen Pompeo (arrived late at 10:15 a.m.), Mr. Albert Sherman, Ms. Janet Slemenda, Mr. Gaylord Thayer, Jr. and Dr.Martin Williams. Dr. Thomas Sterne was absent. Also in attendance was Attorney Donna Levin, General Counsel.

Chair Cote announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance.

The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Dr. Paul Dreyer, Associate Commissioner, Dr. Grant Carrow, Deputy Director, Center for Quality Assurance and Control; Attorney Carol Balulescu, Deputy General Counsel, Office of the General Counsel, and Ms. Joan Gorga, Acting Director, Determination of Need Program.

STAFF PRESENTATION: "PRESCRIPTION MONITORING PROGRAM: OVERVIEW AND ENHANCEMENT INITIATIVES", By Grant Carrow, Ph.D., Deputy Director, Center for Quality Assurance and Control.

Dr. Carrow said in part, "…The Prescription Monitoring Program was established in 1992 by joint regulation between the Board of Pharmacy and the Department of Public Health. We collect prescription records for Schedule II drugs, dispensed at community, clinic and outpatient pharmacies and hospitals. The data is reviewed by the Department and a Medical Review Group, which is comprised of physicians, dentists, other practitioners and pharmacists…In terms of what we are recording and receiving, in terms of the records they are all Schedule II prescriptions, over 2.6 million for FY 2005. About 60% of those are for oxycodone-like products that includes OxyContin, and other opioids such as Percocet. The next highest would be methylphenidate (Ritalin) and a number of other Schedule II drugs. The trends show that there has been a constant increase in the number of prescriptions for oxycodone. In addition, there have been increases in morphine prescriptions, decreases in prescribing of fentanyl, and increases in methadone for pain."

Dr. Carrow noted that it is important, when looking at prescriptions, to look at other measures of dispensing and prescribing – that is unit dosages or grams of a drug, for though the number of prescriptions written may be less for a drug, there may be higher unit dosages or grams of a drug dispensed.

"In the mid 1990s," Dr. Carrow said, "We recognized that there was prescribing of the drug Glutethimide and that drug was not favored for use at that time. Our database indicated that about 100 prescribers were prescribing that drug. We had an educational initiative to urge the prescribers to put their patients on a more appropriate drug. Over the course of our initiative, the number of

prescriptions for Glutethimide which started at about fifty in January 1994 went down to nearly zero. This demonstrates the ability of the program to be used to have targeted educational preventions."

Dr. Carrow noted further, "Our overall goal of our enhancement initiatives is to reduce the impact of prescription drug diversion in Massachusetts and reduce non-medical use and abuse through the optimal use of the Prescription Monitoring Program. Just briefly, we want to be able to improve our analysis of the data to be able to better identify cases needing investigation; improve access to and utilization of the findings for law enforcement, regulatory agencies, and researchers, as well as provide the data to providers and pharmacies themselves, and to be able to intervene in or prevent prescription drug abuse and addiction and diversion; and finally, we are working on partnering with other New England States to address the issues of interstate drug diversion."

Discussion followed, it was noted that it was not the intent of the Drug Monitoring Program to monitor individuals but criminal activity. Dr. Carrow noted the limitations of the data: (1) 25% of the data lacks a customer ID so one can't identify unique individuals; (2) An individual may have more than one ID number or be picking up for other family members under one ID Number. Today's proposed regulations hope to remedy those problems.

NO VOTE/INFORMATION ONLY

PROPOSED REGULATION: INFORMATIONAL BRIEFING ON AMENDMENTS TO 105 CMR 700.000: IMPLEMENTATION OF M.G.L.c.94C (PRESCRIPTION MONITORING PROGRAM):

Dr. Grant Carrow, Deputy Director, Center for Quality Assurance and Control, presented the proposed 105 CMR 700.000 regulations to the Council.

Staff's memo to the Council states: The Drug Control Program proposes to amend regulations to enhance the Massachusetts Prescription Monitoring Program (PMP). The PMP is a critical tool for addressing the problems of illicit use and abuse of prescription drugs in the Commonwealth. The purposes of the enhancements are to improve data quality, increase data utility and utilization, reduce the opportunities for drug diversion and increase prevention of and facilitate interventions in drug addiction and abuse. Specifically, the amendments would:

1. Require pharmacies to obtain positive customer identification before dispensing Schedule II drugs, however the amendments provide for exceptions to this requirement to ensure that patients will not be unreasonably denied access to needed medications;

2. Require pharmacies to report to the Department additional information about Schedule II prescriptions such as name and address of patients. Adding these fields would facilitate sharing of data with practitioners about prescriptions for Schedule II drugs and would enable statistically valid epidemiological analysis of prescription drug use and abuse. The patient information would be confidential and could be disclosed only as provided in the regulations; and

3. Authorize the Department to share information about potential diversion of Schedule II controlled substances with practitioners and pharmacies. By making data available to medical practitioners, the PMP could assist in identifying those at risk or involved in prescription drug abuse and diversion, who then can be referred to appropriate treatment and/or interdiction.

In conclusion, Staff's memorandum stated, "These amendments would enable implementation of a number of the recommendations in the Commonwealth's Substance Abuse Strategic Plan and are one of a number of steps the Drug Control Program is taking to enhance the PMP as part of enhancement initiatives funded in part by the U.S. Department of Justice. While the amendments proposed here are not intended to address every possible area of regulatory enhancement of the PMP, they are a first and necessary step toward enabling the Program to reach its full potential to protect the public health and safety." A public hearing will be held in February 2006; following this the proposed regulations will be brought back to the Council for final action.

NO VOTE/INFORMATION ONLY

REGULATIONS:

REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO 105 CMR 140.000: LICENSURE OF CLINICS (REQUIREMENTS FOR CLINICS THAT PROVIDE MENTAL HEALTH SERVICES):

Attorney Balulescu, Deputy General Counsel, presented the clinic licensure regulations to the Council for promulgation. Atty. Balulescu stated, "The regulation in your packet is substantially the same as that presented to you at the informational briefing in November. The only changes made since that time are further corrections of typographical errors and citations. The Department worked with an advisory group to update the sections of the regulation that set forth requirements for mental health clinics in order to reflect current standards of practice." These regulations were updated last in 1994. The Department has the oversight authority for the licensure and operations of clinics in Massachusetts, including specialized services, such as dental clinics and mental health clinics. A public hearing had been held on December 14, 2005 for comments on these proposed regulations. One person attended and offered written testimony on behalf of the Mental Health and Substance Abuse Corporations of Massachusetts (MHSACM) which stated that, "[b]y clarifying language, eliminating redundancy, and facilitating efficiency and improved services, these proposed changes will have a profound impact on the ability of community mental health clinics to provide high-quality, cost-effective care."

After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve the Request for **Final Promulgation of Amendments to 105 CMR 140.000: Licensure of Clinics**; that the regulations be forwarded to the Secretary of the Commonwealth for promulgation; and that a copy be attached and made a part of this record as **Exhibit No. 14,843**.

REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO 105 CMR 100.000: DETERMINATION OF NEED REGULATIONS (requirings full disclosure by parties of record):

Attorney Carol Balulescu presented the amendments to the Determination of Need Regulations to the Council. Attorney Balulescu noted, "that a public hearing was held on December 14, 2005, no one attended the hearing, nor did anyone submit written comments regarding these changes to the regulation. Accordingly, the Department requests your approval to make these emergency amendments permanent."

Staff's memorandum to the Council provided the following information: "The purpose of these emergency amendments was to require full disclosure by all parties that seek to participate in a Determination of Need application process. The Public Health Council approved these emergency amendments on November 15, 2005 and the Department filed the amendments with the Secretary of the Commonwealth for promulgation the same day."

Staff memorandum stated further, "The Determination of Need (DoN) process affords opportunities to parties of record and other interested persons to comment on DoN Applications, and, in certain instances, to participate in proceedings before the Public Health Council (PHC). The regulation defines parties of record to be, in addition to the applicant, comparable applicants, and various agencies of the Commonwealth, 'any ten taxpayer groups duly registered pursuant to 105 CMR 100.140.' Persons who are not affiliated with ten taxpayer groups (TTGs) have the opportunity to offer oral and written testimony at public hearings conducted by the Department pursuant to 105 CMR 100.410, and may also submit written comments to the Department in accordance with 105 CMR 100.401. The DoN regulation also addresses comments by interested parties in 105 CMR 100.110, which prohibits the applicant, other parties, or their agents or representatives, from initiating any oral or written communication with PHC members regarding a pending application. In recent applications that had been presented to the PHC, comments were provided by TTGs and other interested parties who acted as agents for undisclosed principals. Failure to disclose the party in interest hampered a fair and open discussion of comments by the Department and the PHC, and prevented the ability of PHC members to approximately assess potential conflicts of interest. In addition, PHC members had no way to recognize whether contacts may have violated the above-noted prohibition in 105 CMR 100.110."

In closing, it was stated, "The amendments simply require a full disclosure by TTGs or other commenters who act as agents for other parties, so that the record of all DoN applications will be open and equitable to all participants, including PHC members."

Council Member Maureen Pompeo, stated, " I think this is terrific. It is supposed to be a transparent public process and this does it."

After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve the Request **for Final Promulgation of Emergency Amendments to 105 CMR 100.000: Determination of Need**; that a copy of the emergency amendments be attached and made a part of

this record as **Exhibit No. 14,844**; and that the approved amendments be forwarded to the Secretary of the Commonwealth for final promulgation.

REQUEST FOR EMERGENCY PROMULGATION OF AMENDMENTS TO 105 CMR 100.000: DETERMINATION OF NEED REGULATIONS (regarding dates for nursing home projects):

Dr. Paul Dreyer, Associate Commissioner, Center for Quality Assurance and Control, presented the emergency amendments to the Determination of Need Regulations (DoN) to the Council. Dr. Dreyer said in part, "…These amendments are with respect to construction of new beds, and with respect to previously approved replacement projects. Under the current DoN regulation, the previously approved replacement projects are scheduled to expire on 1/1/2007, and there are 63 replacement projects that have been approved that are due to expire on that date. We have rolled that date forward several times over the past, probably, ten years, and in thinking about what we should do with these projects, going forward, we have come to the conclusion that these projects needn't expire. These are projects in which the Department has determined that the physical plant is such that it warrants replacement. They are not competitive applications…There are a number of factors that have led holders of these replacement projects not to proceed; market conditions, availability of financing, and a host of market factors. The expiration date is really an artificial constraint on the ability of providers to implement these projects, which, again, their non-construction doesn't prejudice any other project. The proposal is to remove the expiration date for these projects. In retrospect, these projects really didn't need expiration date in the first place. The concept of the expiration date is in the competitive context, when you have two applicants competing for one slot. If the first applicant is given the project and can't implement it, then the second applicant ought to have a shot at it. That's a competitive process where it makes sense for DoNs to expire."

Dr. Dreyer continued, "The second amendment is to roll back the next filing date for new nursing home beds to May 1, 2010…Folks often think that we are going to need more nursing home beds because the population is aging. What we are seeing is that the utilization rate of the oldest folks is actually declining faster than their numbers are growing. The analysis before you shows that in 2010, there will be a surplus of around 5,000 beds…"

Dr. Dreyer said in conclusion, "These are emergency amendments due to: (1) the next filing date for new nursing home beds is in May currently and we don't want to forestall any lack of clarity about the fact that that should not happen, and (2) we also want to give those with replacement projects, who are interested in implementing them, the ability to go forward with all due dispatch."

Council Member Sherman added, "I was wrong and you were right. We don't need anymore beds. We have been discussing this for 15 years." Council Member Sherman inquired about the BANYL beds (Beds Approved Not Yet Licensed). "You are going to institute the rules and then you are going to have a public hearing afterwards", inquired Mr. Sherman. Discussion followed. Dr. Dreyer noted, "BANYL projects would expire under this proposal, and there are people concerned about that. I recommend to the Council that we get comments on this issue at the public hearing and make any appropriate disposition about BANYL beds at that time. I would suggest since there has been no activity on these projects in 15 years, no one would be prejudiced by the fact that the amendments

are promulgated now, if we hold a public hearing, and consider changes after the fact." During the discussion, Dr. Dreyer further noted that the Department has spoken to some holders but not all of them; and that the Department presented this proposal to the Mass. Extended Care Federation, which did not have a strong objection.

Council Member Sherman noted his concern about potential legal costs to the Department to defend this proposal. Council Member Sherman asked whether staff could postpone this proposal for another month until the next meeting of the Council so that the holders could comment on it. Dr. Dreyer commented that he feels "due process has been afforded the holders of the projects. The projects are scheduled to expire and the holders are aware of that…" Council Member Maureen Pompeo added, "…I don't know what happened today…I like to support staff. I have great faith in this staff but it seems to me that on this particular issue there is an issue of process. To speak to some holders but not all holders, particularly when there is a limited amount, seems from an outside perspective, somewhat unfair. I know that, if I were sitting on the reverse side of the table, I would have the same concerns about the BANYL beds as the replacement beds. They are the same market conditions. It is true that there is a competitive element here, but the same market conditions, the same reason that replacement beds haven't been replaced, are the same reasons new beds haven't been built…Perhaps one way to do this would be to separate these two because they are two different issues."

Attorney Donna Levin, General Counsel, said that the Council could take both issues to the public hearing together but one as a non-emergency regulation. Council could accept this emergency regulation as it is presented [for the replacement projects] and remove the BANYL beds from emergency promulgation status; the BANYL would go to public hearing in an informational status instead. Discussion and the vote on this item were postponed until later in the meeting, to give staff time to work out the amended language. Staff came back with amended language after docket items 4a and 4b were heard.

Upon staff's return on docket item 3c the following occurred:

Deputy General Counsel Carol Balulescu explained the amendments, "We begin on one of two, that has the current regulation. There is a two-page attachment and, in the middle, Item 2 is the Mandatory Terms and Conditions in the current regulation. If you look at C 1 ½, Item 1, the current language states the period of authorization for unimplemented determinations shall be extended until January 1, 2007. We propose to insert in that line, 'for any new convalescent nursing and rest home projects.' In other words, the language remains the same for the BANYLs, even in the emergency regulations. On the second, page, where we had the proposed amendments, Item No.1 becomes Item No.2, and will begin with not withstanding C 1 ½, item 1, and then we have the language on the replacement projects, and then 2 becomes 3."

In summary, Attorney Balulescu said, "The Emergency Regulation will keep in the language for BANYLs. It will remove the expiration date for the replacement projects. There will be three sections rather than two, under C 1 ½. At the public hearing, we will hear comments from anyone who is interested in commenting on the replacement projects. We will also hear comments from anyone who is interested in commenting on the BANYLs because, under the language, they still are due to expire January 1, 2007. Folks will be free to comment either that they should never expire,

that the expiration date should be extended, or that they should expire as the regulation states. That's a single action and a single hearing."

After consideration, upon motion made and duly seconded, it was voted unanimously to approve the **Request For Emergency Promulgation of Amendments to 105 CMR 100.000: Determination of Need Regulations (regarding dates for nursing home projects);** that a copy of the approved amendments be attached and made a part of this record as **Exhibit No. 14,845**, and that a copy be forwarded to the Secretary of the Commonwealth for promulgation.

DETERMINATION OF NEED PROGRAM:

COMPLIANCE MEMORANDUM:

PREVIOUSLY APPROVED DON PROJECT NO. 2-3A88 OF ST. VINCENT HOSPITAL – PROGRESS REPORT ON COMPLIANCE WITH CONDITIONS OF APPROVAL FOR TRANSFER OF OWNERSHIP:

Ms. Joan Gorga, Acting Director, Determination of Need Program, presented the St. Vincent Hospital Progress Report Information to the Council, "In December 2004, the Council approved the transfer of ownership and original licensure of the hospital by Vanguard Health Systems. Condition #5 of the Determination of Need required the hospital to appear before the Council to report on compliance with the conditions of the DoN, including free care, interpreter services, community benefits and meetings with community organizations. DoN Staff invited, by registered mail and several telephone calls, all of the interested parties which were registered at the time of transfer. However, no written comments were received. St. Vincent Hospital prepared a progress report and staff has summarized its activities in each condition in the compliance memo to the Council."

Ms. Gorga continued, "Among the conditions on which St. Vincent reported was free care. St. Vincent reports that the actual free care provided at the hospital in 2005 was 2.11%, a decrease of .52% from the percentage of 2.63 stipulated in the condition. St. Vincent attributes this decrease to a change in the regulations by the Division of Health Care Finance and Policy that precluded the hospital from billing the uncompensated care pool for primary services. In order to ensure that patients received prompt access to care, the hospital contracted with the nearest neighborhood health center where the hospital's teaching faculty provided free care to the St. Vincent patients. In September, the Hospital applied for and received an exemption to the regulations and, once again, began to see free care patients. A copy of the waiver has been included in the materials you received. Staff has been in touch with the Division of Health Care Finance and Policy, who has indicated that St. Vincent was correct in following the rules and regulations, and who has also indicated that they are convinced that this temporary situation in 2005 was responsible for the decrease in free care at St. Vincent. Based on this discussion of free care, as well as the response of St. Vincent to the other conditions, as summarized in the memorandum to the Council, Staff finds the St. Vincent Hospital substantially complying with all conditions, one through five, and recommends that St. Vincent return to the Council in six months to report on further progress."

A brief discussion was held and the applicant was available but did not testify. The Mass. Healthcare Coalition did not submit comments or testify. After consideration, upon motion made

and duly seconded, it was voted unanimously to approve Staff's Recommendation that **Approved DoN Project No. 2-3A88: Acquisition of St. Vincent Hospital by Vanguard Health Systems, Inc.** submit in six months (July 2006) a progress report on conditions No.1 through No.5, and that Staff be directed to report its findings to the Public Health Council. A copy of Staff's memorandum to the Council, dated January 24, 2006, is attached and made a part of this record as **Exhibit No. 14,846.**

PREVIOUSLY APPROVED DoN PROJECT NO. 4-3A89 OF METROWEST MEDICAL CENTER – PROGRESS REPORT:

Ms. Joan Gorga, Acting Director, Determination of Need Program, presented the MetroWest Medical Center to the Council. Ms. Gorga said in part, "…In December 2002, the Council approved the transfer of ownership and original licensure of MetroWest Medical Center in Framingham and Leonard Morse Hospital in Natick, resulting from the acquisition of the Medical Center by Vanguard Health Systems."

Ms. Gorga noted, "Condition 17 of the DoN required MetroWest Medical Center to appear before the Council to report on compliance with the conditions of the DoN, including free care, interpreter services, capital investment, and 13 other concerns identified in an agreement negotiated and signed at the time of the transfer by the Medical Center and several community groups, many represented by the MetroWest Community Health Care Coalition."

Ms. Gorga continued, "MetroWest has prepared a progress report and the Coalition and the MetroWest Community Health Care Foundation have submitted comments on the progress report, which have been summarized in the compliance memo which you received. The Coalition has noted in its comments that it is pleased with the overall progress, that the hospital has made significant outreach efforts to the community and that they are working together in good faith, and on a regular basis. Staff is pleased to note that there has been progress in the past year and that the Coalition reports they have had productive communication with MetroWest. All three commenters noted the capital improvements which Vanguard Health Systems have made on the MetroWest and the Leonard Morse campuses, including upgrades to equipment and to the infrastructure."

Staff's memorandum to the Council states, "Condition No.1 stipulates that MetroWest allocate 3.17% of gross patient service revenue to free care for an indefinite period. However, MetroWest reports that the actual total free care provided was 2.76%, a decrease of .41% from the percentage stipulated in the condition. MetroWest reports that the free care percentage from January 1, 2005 through September 30, 2005 is within the range of monthly variations in free care that MetroWest has recorded over the past several years and also notes that the hospital is no longer making the determination that a patient is eligible for free care. New Health Care Finance and Policy regulations related to emergency room and free care and the new Virtual Gateway System have now moved this determination from the hospital to MassHealth. MetroWest indicates that its outpatient clinics, and emergency, inpatient and outpatient departments have full-time financial counselors to explain free care benefits and to assist patients in applying for MassHealth and free care."

In its comments the Coalition notes that at the time of filing, the level of free care provided by the Medical Center was 2.66%, which is less than the level at the time of the license transfer and less

than the present percentage. The Coalition notes that there have been variations in the rate over the years. The Coalition states that it closely monitors the level of free care, meets regularly with MetroWest staff on this and other issues and would discuss the free care level with the staff if MetroWest was not meeting its free care obligation.

In response to the MetroWest data, Staff notes that a reduction in free care services at acute care hospitals has been seen statewide in recent years through the Progress Reports of other health care facilities. However, because of the change in enrollment procedures, Staff cannot find with certainty that MetroWest does or does not meet the 2.76% requirement. Based on the information provided by MetroWest and the Coalition, Staff has determined that MetroWest is in full compliance with condition No. 1 to the extent possible under the new procedures.

In conclusion, Ms. Gorga said, "Staff finds that MetroWest is substantially complying with conditions 1 through 17 of the Determination of Need. Staff notes the positive relationship that MetroWest and the Coalition have developed. Since this is the first progress report and many activities are in progress, Staff recommends that MetroWest return to the Council in one year to report on further progress. This is in keeping with condition No. 17 of the original DoN."

The applicant was present but did not address the Council. Nancy King of MetroWest Community Health Coalition added, "The report doesn't adequately convey the level of cooperation between Staff and the Coalition and we want to commend them for that."

After consideration, upon motion made and duly seconded, it was voted unanimously to approve Staff's recommendation that **Approved DoN Project No. 4-3A89: Acquisition of MetroWest Medical Center by Vanguard Health Systems, Inc.** return to the Council in one year to further report on their progress. Staff's memorandum to the Council, dated January 24, 2006, is attached and made a part of this record as **Exhibit Number 14,847**.

The meeting adjourned at 11:25 a.m.

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Paul J. Cote, Jr.
Chair

LMH/lmh